INTERFERENCE BETWEEN GSM MOBILE PHONES AND PACE-MAKERS: IN VITRO EVALUATION OF INTERACTION MECHANISMS

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Abstract- Aim of this study was to in-vitro evaluate the effectiveness of the filtered feedthru assembly used to filter out the electromagnetic interference at the input stage of implantable pace-makers. We used three modified pace-makers of the same model, with an electrical connection to the output of the input sensing amplifier. The pace-makers differed for the level of protection against electromagnetic interference. We used a dual-band mobile phone. For each pace-maker the output of the sensing amplifier was monitored in 4 status: 1) no inhibition signal; 2) inhibition signal with amplitude 50% greater than the sensing threshold; 3) inhibition signal slightly lower than the sensing threshold; 4) inhibition signal slightly greater than the sensing threshold. For each pace-maker, evaluation has been performed in basal condition (no radiated power), during ringing and during talking. We found that the PMK with only the block capacitor shows asynchronous pacing and inhibition, while the other two PMKs do not interfere with the mobile phone, in any stage and for any mobile status.

Keywords - Electromagnetic interference, pace-maker, GSM, interaction mechanisms.

I. INTRODUCTION

Since 1994, several researches reported data concerning the adverse effects of electromagnetic fields radiated from mobile phones against implantable pace-makers (PMK) [1-5].

These studies have evinced that cellular phones may induce pulse inhibition, noise reversion, false triggering, sensitizing and desensitizing phenomena.

The majority of these studies focused on the assessment of a safety distance and on the systematic evaluation of PMK models in the market. Few studies investigated the mechanisms by which electromagnetic fields interact with PMK.

Most implantable PMKs employ electromagnetic interference filters located internally on the hybrid circuit. Although such filters reject high frequency RF signals, they allow the passing of signals with a frequency range similar of that of atrial and ventricular depolarization (20-50 Hz).

The aim of this study was to compare three solutions for filtering the radiofrequency interference before it reaches the sensing amplifier. The first one uses a capacitor which short circuits high frequency signals (5 nF); the second one uses a ceramic capacitor; the third one uses a filtered feedthru assembly, consisting of an hermetically sealed mechanism used to connect the electronics inside the PMK enclosure to the outside connection block and of a separate capacitive filter. The comparison has been performed by using three modified PMKs, each adopting one of the above mentioned filtering solutions. The PMKs had been modified in order to have an electronic connection with the output of the sensing amplifier. By comparing the output signals of the sensing

amplifier, we could also investigate the interaction mechanisms.

II. METHODOLOGY

We used three versions of the PMK MINIOR 100 (SORIN BIOMEDICA, Italy): one with the block capacitor; one with the ceramic capacitor and one with the filtered feedthru assembly. The three PMKs had been properly modified in order to have an electrical connection to the output of the sensing amplifier (figure 1).



Fig. 1. Modified PMK.

All PMKs were programmed with the same parameters, shown in table I.

TABLE I PMK PARAMETERS

PMK MINIOR 100 – SORIN BIOMEDICA			
PARAMETER	VALUE		
Stimolation mode	SSI		
Heart Rate	70 bpm		
Hysteresis	0 bmp		
Stimolation polarity	Bipolar		
Amplitude	5.0 V		
Duration	0.50 ms		
Rilevation polarity	Bipolar		
Sensibility	0.6 mV		
Refractory period	250 ms		

In order to avoid any spurious interference carried on by the extra electrical connection, the PMKs were inserted into an aluminum box. Inside the box, we also put an instrumentation amplifier (INA118P, Burr-Braun, USA), for conditioning the output signal. The output of the amplifier was connected to a digital acquisition system through BNC connectors and shielded cables. The PMK was inserted into the aluminum box so that only the silicon connection head

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was exposed to the mobile phone radiation (figure 2). The catheter tip was immersed into a 0.9% saline solution contained in a plexiglass box (figure 3). The inhibition signal was delivered through the saline solution by cloride-silver square plates (2cmx2cm), avoiding any ohmic contact with the catheter tip. Inhibition signal (EN 50061, 1.6 Hz) was provided by a signal generator (Philips, PM 5139), and acquired by the digital acquisition system (DAQCard 1200, National Instruments, sampling frequency 1000 resolution 12 bit). A 1GHz digital oscilloscope was also used to monitor both the inhibition signal and the PMK output. The complete experimental setup is shown in figure 3.

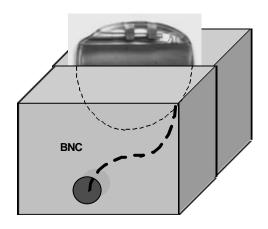
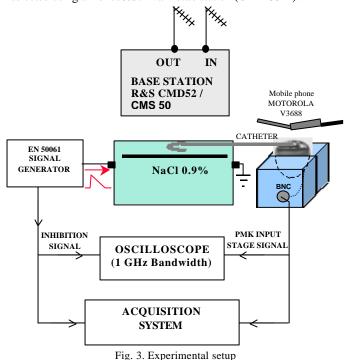


Fig. 2. Insertion of the PMK into the aluminum box.

The mobile phone used was the MOTOROLA V3688. Mobile emitted power and communication protocols were selected using a Rohde&Schwarz base station (CDM 55M).



rig. 5. Experimental setup

For each PMK, the output of the sensing amplifier was monitored in 4 PMK status: 1) no inhibition signal; 2)

inhibition signal with amplitude 50% greater than the sensing threshold; 3) inhibition signal slightly lower than the sensing threshold; 4) inhibition signal slightly greater than the sensing threshold. For each PMK status, 3 situations for the mobile phone have been analyzed: basal condition (no radiated power), ringing and talking (1 minute each, table II). Discontinuous Trasmission protocol has been deactivated

All the tests have been done using 900 MHz GSM and 1800 MHz GSM, with the mobile power class set to the maximum (2 Watt for 900 MHz, 1 Watt for 1800 MHz).

TABLE II
EXPERIMENTAL PROTOCOL

_4	PROTOCOL		
stage	Inhibition signal amplitude	Mobile status	
1 2 3 4	0 V 50% greater than the sensing threshold Slightly greater than the sensing threshold Slightly lower than the sensing threshold	1) Off 2) Ringing 3) Talking	

III. RESULTS

Tables III and IV report the noise levels (expressed in mV^2 , 0-500 Hz) obtained for the 3 PMKs at each of the 4 stages of the test, for 900 MHz and 1800 MHz, respectively.

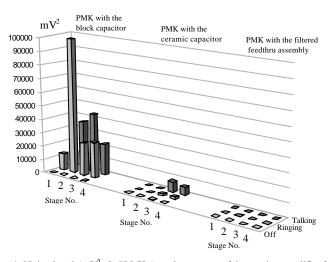
TABLE III. RESULTS: noise level (mV², 0-500 Hz) at the output of the sensing amplifier (900 MHz)

sensing amplifier (900 MHz)				
PMK	Stage	900 MHz		
type	No.	Basal	Ringing	Talking
Block capacitor	1	71.47	12200.00	11100.00
	2	82.23	99200.00	36200.00
	3	123.78	24100.00	43600.00
	4	97.77	26200.00	22800.00
Ceramic capacitor	1	18.89	19.00	18.70
	2	21.51	25.30	26.07
	3	106.00	1300.00	7500.00
	4	22.80	1500.00	5800.00
Filtered feedthru assembly	1	14.26	15.74	15.87
	2	16.29	21.79	20.25
	3	15.20	18.00	21.30
	4	13.99	16.09	17.31

TABLE IV. RESULTS: noise level (mV 2 , 0-500 Hz) at the output of the sensing amplifier (1800 MHz)

PMK	Stage	1800 MHz		
type	No.	Basal	Ringing	Talking
Block	1	73.37	157.02	382.25
	2	77.45	153.09	213.40
	3	101.27	250.99	360.77
	4	50.21	141.86	565.15
	1	18.68	18.71	18.68
nic	2	179.13	191.16	182.48
Ceramic	3	108.00	98.20	63.95
C S	4	18.40	18.46	20.58
Filtered feedthru assembly	1	16.52	15.82	16.28
	2	16.38	20.91	17.93
	3	16.50	19.00	19.80
F fe as	4	15.38	19.08	17.70

900 MHz 1800 MHz



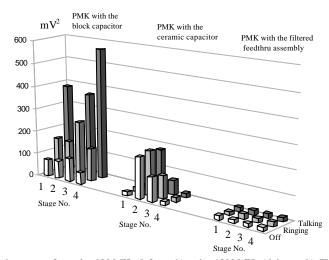


Fig. 4: Noise level (mV^2 , 0-500 Hz) at the output of the sensing amplifier for the tests performed at 900 MHz (left graph) and at 1800 MHz (right graph). The noise level for the three tested PMKs are reported, for the 4 analyzed stages, and during basal conditions of the mobile phone (no emitted power, white bars), during ringing (light grey bars) and during talking (dark grey bars).

Figure 4 shows the results during basal (white bars), ringing (light grey bars) and talking (dark grey bars). Note that the PMK with the block capacitor presents noise levels higher than that with the ceramic capacitor and with the filtered feedthru assembly during talking and ringing phases both at 900 MHz and at 1800 MHz. In addition, at 900 MHz, noise levels are significantly higher than during 900 MHz. Figure 5 shows the power spectral densities of the noise during ringing (left) and talking (right) at 900 MHz for the 3 PMKs, when inhibition signal amplitude is set to 0V.

For the PMK having only the block capacitor, we observed asynchronous pacing when the PMK was inhibited (inhibition signal amplitude 50% greater than the sensing threshold) both in ringing and talking phases and both at 900 and 1800 MHz. When the inhibition signal amplitude was set to 0V, we had pulse inhibition and asynchronous pacing, during ringing and talking, both at 900 MHz and 1800 MHz.

When inhibition signal is slightly greater than the sensing threshold, we had pacing both during ringing and talking, at 900 and 1800 MHz. Figure 6 shows the PMK input stage signal in this case. The pacing could be to the asynchronous EMI protection mode, or could due to a decrease of the inhibition signal caused by the interference with the 900 and 1800 MHz GSM signal.

When inhibition signal amplitude is slightly lower than the sensing threshold, we had asynchronous pacing during ringing and talking at 900 MHz. At 1800 MHz, we did not observe any interference.

The PMK with the ceramic capacitor did not exhibit any interference when inhibition signal amplitude is 50% greater and slightly greater than the sensing threshold and when it is 0V. Although the noise level at the output of the sensing amplifier is higher during talking and ringing at 900 MHz than during basal conditions, we did not observed any

interference phenomena when the inhibition signal amplitude was both slightly lower or greater than the sensing threshold. No interference effects have been observed at 1800 MHz.

The tests with the PMK having the filtered feedthru assembly revealed no interference phenomena in none of the 4 values of the inhibition signal amplitude.

IV. DISCUSSION

Although the improvements in PMK technology and design, PMKs remain to some extent susceptible to interference from external sources of electromagnetic energy.

Recently, a revolutionary filtered feedthru design has been introduced, which prevents unwanted signals from entering the PMK enclosure. Signals inside the PMK case could essentially overwhelm the internal filter which blocks the signals outside the PMK's normal bandpass. Such interference signal can thus be sensed. The filtered feedthru prevents the undesired signals to access to the PMK enclosure.

Our results show that the noise in the frequency band 0500 Hz for the PMKs with the ceramic capacitor is much lower than that observed for the PMK with the block capacitor only. We can hypothesized that this noise is somehow demodulated at the input stage of the PMK when the 900 MHz or 1800 MHz carriers are not filtered out by the block capacitor.

The ceramic capacitor, instead, guarantees an higher attenuation at these frequencies, and thus the demodulated noise in the 0-500 Hz frequency band is no more detectable.

We also found that the PMK with only the block capacitor shows asynchronous pacing and inhibition, while the other two PMKs do not interfere with the mobile phone, in any stage and for any mobile status.

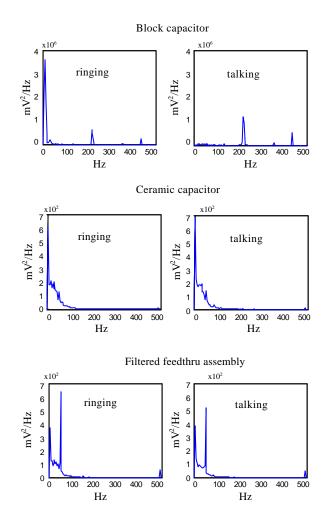


Fig 5. Power spectral densities of the noise during ringing (left) and talking (right) at 900 MHz for the 3 PMKs, when inhibition signal amplitude is 0V.

V. CONCLUSIONS

In this study we documented the superior performances of the filtered feedthru assembly for electromagnetic immunity of PMKs. We also reported a possible mechanism explaining the reduction of the noise at the output of the input PMK stage in the band 0500 Hz. Our results may also be useful for stratifying the interference risk of PMK already implanted.

ACKNOWLEDGMENT

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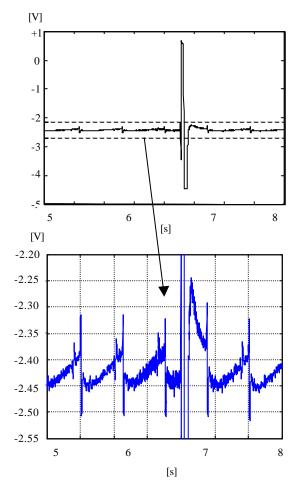


Fig. 6. Block capacitor PMK input stage signal during talking (900 MHz) when inhibition signal is slightly greater than the sensing threshold.

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